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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,380	07/25/2002	Aharon Shulov	24871	9209

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,380	SHULOV ET AL.	
	Examiner	Art Unit	
	Randall Winston	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0402*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the species *Crotalidae* in its response to the restriction requirement of 12/14/2004 is acknowledged. The traversal is based on the grounds that applicants respectfully note that the International Preliminary Report does not contain indication of lack of unity of invention between the claims of the underlying PCT application, which were substantially similar to the claims presently pending in this application. For these reasons, unity of invention clearly exists between all claims because the special technical feature common to all of the claims is the steps of the method.

Applicant's argument is not found persuasive because, as Examiner explained in the previous restriction requirement of 127/14/2004, the following claim(s) are generic: claims 1-18. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

For claims 1 and 14, applicant is required to elect one species from the Markush group of *Atractaspidae, Elapidae, Crotolidae, Hydrophidae, Viperidae* because each claimed snake species is not functional equivalent to produce the same product (i.e. non-toxic fraction isolated from snake venom) results.

Accordingly, the search for each of the above inventions is not co-extensive particularly with regard to the literature. Further, the reference which would anticipate

the invention of one group would not necessarily anticipate or even make obvious the other group.

The restriction requirement is still deemed proper and is therefore made final.

Please note: Claims 1-3 and 5-18, readable on the elected species, will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim s 1, 3 and 14 are rendered vague and indefinite by the term "*Crotolidae*". The above term is misspelled. The correct spelling is "Crotalidae." Correction is required.

Claim 6 recites the indefinite terms of "derivative". The metes and bounds of the above terms cannot be clearly delineated as the specification fails to set forth the metes and bounds of what is encompassed.

Claim 7 states the phrase "use". Since claims 7 does not set forth any steps involved in the method /process of "use", it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites without any active, positive steps delimiting how this use is actually practiced.

Claim 7 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1-3, 5-8 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Politi et al (US 6,057,297).

Applicant claims a pharmaceutical composition for use as an analgesic (i.e. relief of pain) comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqueous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake family is *Crotalidae* (i.e. *Crotalus adamanteus*) in combination with a pharmaceutically acceptable carrier.

Politi et al. anticipate the claimed invention (see, e.g., example 8 and column 3 lines 52-55) because Politi et al. teach a method for isolating a substantially non-toxic fraction from snake venom (i.e. Politi et al.'s pharmaceutical composition can be taken orally, therefore, one of ordinary skill in the art would not expect a substantially toxic substance to be taken orally), wherein said fraction has an analgesic effect (i.e. Politi et al. teach that it's pharmaceutical composition treats inflammatory diseases whereas pain is associated with inflammation) comprising applying whole venom to an ion exchange column (i.e. the ion-exchange column is DEAE Spehadex A-50 resin) and eluting the fraction with an aqueous buffer (i.e. the buffer is NaCl) , wherein said snake family is *Crotalidae*. Therefore, the reference is deemed to anticipate the claim invention.

{Please Note: Claims 1-3, 5-8 and 11 are product by process claims. Therefore, even if the product is made by a different method, it is appropriate to reject the above claims under both U.S.C 102 and 103 if the product in the reference reasonably appears to be the same. In this case, the product appears to be the same because it is a non-toxic venom product purified using ion-exchange chromatography that has pharmaceutical activity that relates to pain relief}

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 5-18 are rejected under 35 US 103(a) as being unpatentable over Politi et al. (US 6,057,297).

Applicant claims a pharmaceutical composition for use as an analgesic (i.e. relief of pain) comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqueous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake family is *Crotalidae* (i.e. *Crotalus adamanteus*) in combination with a pharmaceutically acceptable carrier.

Politi et al. teach (see, e.g., example 8, column 4 lines 14-18, column 3 line 52-55) a pharmaceutical composition for use as an analgesic to relieve pain (i.e. Politi et al. teach that it's pharmaceutical composition treats inflammatory diseases whereas pain is associated with inflammation) comprising a substantially non-toxic fraction (i.e., Politi et al.'s pharmaceutical composition can be taken orally, therefore, one of ordinary skill in the art would not expect a substantially toxic substance to be taken orally) isolated from snake venom having the characteristics of a fraction purified by ion-exchange chromatography (i.e. by the ion-exchange column of a DEAE Sephadex A-50 resin) and eluting the fraction with an aqueous buffer (i.e. buffer is NaCl), wherein Politi's non-toxic purified fraction would also intrinsically have an analgesic effect after a lag period when administered, and wherein said snake family of isolated snake venom is also from *Crotalus adamanteus* in combination with a pharmaceutical acceptable carrier.

Politi et al. do not expressly teach its purification method is performed by the claimed invention's purification method of Mono Q ion-exchange chromatography and the topical administration and/or the parenteral administration of the claimed non-toxic purified fraction and eluting the fraction with buffers such as the Tris-HCL buffer or the ammonium acetate buffer. However, based upon the overall beneficial teachings provided by Politi et al, the result-effective adjustment of conventional working conditions therein (e.g., the substitution of one ion-exchange column for another ion-exchange column for the same purpose of achieving a purified fraction and the topically and/or the parenteral administration of said fraction and the substitution of one functionally equivalent buffer for another), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Coe
5-27-05
SUSAN COE
PRIMARY EXAMINER